

# **EXHIBIT F**

# Abdominal Sacrocolpopexy: A Comprehensive Review

Ingrid E. Nygaard, MD, MS, Rebecca McCreery, MD, Linda Brubaker, MD, AnnaMarie Connolly, MD, Geoff Cundiff, MD, Anne M. Weber, MD, MS, and Halina Zyczynski, MD, for the Pelvic Floor Disorders Network\*

**OBJECTIVE:** To summarize published data about abdominal sacrocolpopexy and to highlight areas about which data are lacking.

**DATA SOURCES:** We conducted a literature search on MEDLINE using Ovid and PubMed, from January, 1966 to January, 2004, using search terms “sacropepy,” “sacrocolpopexy,” “sacral colpopexy,” “colpopexy,” “sacropepy,” “colposacropepy,” “abdominal sacrocolpopexy” “pelvic organ prolapse and surgery,” and “vaginal vault prolapse or surgery” and included articles with English-language abstracts. We examined reference lists of published articles to identify other articles not found on the electronic search.

**METHODS OF STUDY SELECTION:** We examined all studies identified in our search that provided any outcome data on sacrocolpopexy. Because of the substantial heterogeneity of outcome measures and follow-up intervals in case studies, we did not apply meta-analytic techniques to the data.

**TABULATION, INTEGRATION, AND RESULTS:** Follow-up duration for most studies ranged from 6 months to 3 years. The success rate, when defined as lack of apical prolapse postoperatively, ranged from 78–100% and when defined as no postoperative prolapse, from 58–100%. The median reoperation rates for pelvic organ prolapse and for stress urinary incontinence in the studies that reported these outcomes were 4.4% (range 0–18.2%) and 4.9% (range 1.2% to 30.9%), respectively. The overall rate of mesh erosion was 3.4% (70 of 2,178). Some reports found more mesh erosions when concomitant total hysterectomy was done, whereas other reports did not. There were no data to either support

or refute the contentions that concomitant culdoplasty or paravaginal repair decreased the risk of failure. Most authors recommended burying the graft under the peritoneum to attempt to decrease the risk of bowel obstruction; despite this, the median rate (when reported) of small bowel obstruction requiring surgery was 1.1% (range 0.6% to 8.6%). Few studies rigorously assessed pelvic symptoms, bowel function, or sexual function.

**CONCLUSION:** Sacrocolpopexy is a reliable procedure that effectively and consistently resolves vaginal vault prolapse. Patients should be counseled about the low, but present risk, of reoperation for prolapse, stress incontinence, and complications. Prospective trials are needed to understand the effect of sacrocolpopexy on functional outcomes. (Obstet Gynecol 2004;104:805–23. © 2004 by The American College of Obstetricians and Gynecologists.)

Physicians caring for women are likely to encounter pelvic organ prolapse with increasing frequency because the population is aging. Approximately 200,000 women undergo inpatient procedures for prolapse in the United States each year.<sup>1</sup> One in 3 women who underwent surgery for prolapse or urinary incontinence underwent a repeat operation within 4 years in a study of women in a large health maintenance organization.<sup>2</sup> Despite this high failure rate, data are lacking as to which procedure for prolapse provides optimal effectiveness and safety. This review will summarize what is known about sacrocolpopexy, the main abdominal approach to prolapse surgery, and highlight areas lacking data. The evolution of the procedure, technical variations, concomitant surgeries, complications, and outcomes will be reviewed.

## SOURCES AND STUDY SELECTION

We conducted a literature search on MEDLINE using Ovid and PubMed, from January, 1966 to January, 2004, using search terms “sacropepy,” “sacrocolpopexy,” “sacral colpopexy,” “colpopexy,” “sacropepy,” “colposacropepy,” “abdominal sacrocolpopexy,” “pelvic organ prolapse and surgery,” and “vaginal vault prolapse or surgery.” Only articles with an English abstract

*From the University of Iowa Carver College of Medicine, Iowa City, Iowa; Baylor College of Medicine, Houston, Texas; Loyola University, Chicago, Illinois; University of North Carolina at Chapel Hill, Chapel Hill, North Carolina; Johns Hopkins School of Medicine, Baltimore, Maryland; National Institute for Child Health and Human Development, Bethesda, Maryland; and Magee Womens Hospital, Pittsburgh, Pennsylvania*

\*For a list of Steering Committee members of the Pelvic Floor Disorders Network, see Appendix.

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were included. We included other relevant articles from the reference list of evaluated articles. All identified articles that reported on some aspect of outcome of abdominal sacrocolpopexy were included in the review. Meta-analytic techniques were not applied to these data because of the substantial heterogeneity of outcome measures and follow-up intervals in case studies. The final manuscript draft was then reviewed for completeness by 5 additional urogynecologists; 2 further articles were identified and subsequently included in the review.

## RESULTS

### Historical Evolution of Sacrocolpopexy

The modern surgeon should have an understanding of those techniques that work well, and those that have been abandoned because of lower efficacy or more complications. In the early decades of the 20th century, procedures for apical support included the Manchester or Mayo operations from the vaginal approach, and from the abdominal approach, one of several procedures that fixed the vagina to the abdominal wall.<sup>3</sup> Because of the high rate of recurrent enterocele, in 1957 surgeons began anchoring the vaginal apex posteriorly, approximating the posterior uterine fundus to the anterior longitudinal ligament.<sup>4</sup> Lane<sup>5</sup> first advocated an intervening graft between the vagina and sacrum to overcome excessive tension. Birnbaum<sup>6</sup> felt that the sacral promontory was too anterior for mesh placement, given that the upper vagina is normally directed into the hollow of the sacrum,<sup>7</sup> and instead placed mesh at the level of S-3–S-4. After a life-threatening hemorrhage using this site, Sutton advocated anchoring the graft higher, at the S-1–S-2 level, where the middle sacral artery was more easily visualized and avoided,<sup>8</sup> a change that had no detectable negative effect on the vaginal axis.<sup>9</sup>

To decrease graft detachment from the vaginal apex, Snyder and Krantz<sup>10</sup> extended the graft along the full length of the rectovaginal septum. Addison et al<sup>11</sup> initially used a folded conical graft configuration to maximize the surface area for mesh attachment, but because of more mesh erosions, changed to 2 separate graft strips sutured with monofilament sutures.<sup>12</sup> This 2-strap approach also permitted the surgeon to exert differential tension on the anterior and posterior grafts, thereby potentially decreasing urinary incontinence caused when the urethrovesical angle is straightened too much. Several authors used autologous or allogenic grafts in attempts to decrease mesh erosion.<sup>13,14</sup>

The more recently described sacral colpoperineopexy was developed to treat patients with vaginal vault prolapse combined with perineal descent.<sup>15</sup> Cundiff et al<sup>16</sup> extended the posterior graft to the perineal body by the

abdominal route in 19 women without an increase in complications. Sullivan<sup>17</sup> described a “total pelvic mesh repair” which resolved defecatory symptoms in three fourths of patients, but at the price of a 10% reoperation rate from surgical complications. Visco et al<sup>18</sup> reported more mesh erosions when a combined vaginal and abdominal, rather than an all-abdominal approach was used for sacral colpoperineopexy.

### Concomitant Surgical Procedures, Including Hysterectomy

Surgeons employ sacrocolpopexy for loss of apical support but frequently do concomitant procedures to address other support defects. Although early surgeons did not describe concomitant culdoplasty, many subsequent authors advocated obliteration of the cul-de-sac, either using the Moschcowitz or Halban technique,<sup>11–13,16,19</sup> although this procedure is not used by all surgeons.<sup>6,10</sup> Based on anecdotal surgical experience, some of this article’s authors believe that patients undergoing culdoplasty have increased postoperative defecatory difficulty. This question has not been formally tested.

Similarly, most early descriptions of sacrocolpopexy describe closing the peritoneum over the graft and vagina in an attempt to decrease the risk of bowel obstruction and mesh erosion. However, it is not clear whether this additional step is needed. In a small study of 35 women, 3 had postoperative bowel obstructions.<sup>20</sup> The authors noted that while all 3 had careful reperitonealization, all had intestine trapped under the mesh, causing the obstruction. In a recent case report of a woman who developed an entero-mesh vaginal fistula 4–6 months after sacrocolpopexy after “minimal reperitonealization,”<sup>21</sup> the authors cautioned that although reperitonealization has been abandoned in certain procedures, it might be useful in this setting so that the small bowel cannot directly appose the mesh. It is also likely that the more inert the graft that is used, the less likely erosions or fistulae will be. Because mesh erosions occur infrequently, it is unlikely that this question will be answered in a randomized trial.

Some surgeons advocate either a posterior colpoperineorrhaphy<sup>9,22</sup> or defect-directed posterior repair,<sup>12</sup> but others suggest that posterior support can be adequately achieved from the abdominal approach if the posterior strap is carried down the rectovaginal septum such that there is continuity between the perineal body, posterior rectovaginal septum, and mesh.<sup>10,16,19</sup>

Early authors suggested concurrent anterior colporrhaphy with sacrocolpopexy.<sup>3,5,6,22</sup> As retropubic urethropexy became a standard treatment for stress urinary incontinence, many surgeons began to use one of its variations in conjunction with sacrocolpopexy.<sup>10–12</sup> Al-



though this approach is indicated when the patient has stress incontinence, the approach to a patient without stress incontinence is less clear. There is weak evidence that retropubic urethropexy is effective in treating anterior vaginal prolapse. Addison<sup>19</sup> compared 20 patients treated with retropubic urethropexy with 19 patients treated with paravaginal defect repair and reported no differences in anterior vaginal support.

Concurrent hysterectomy has a theoretic risk of increasing infection or erosion of the graft, given the chance of contamination from vaginal microbes; however, current evidence is contradictory, and no randomized trials address this issue. Imperato et al<sup>23</sup> described 71 women who underwent sacrocolpopexy, 57 with concurrent hysterectomy; 21 of 57 women had synthetic mesh, whereas in the other 36, the vaginal apex was directly approximated to the anterior vertebral longitudinal ligament. Mesh "rejection" occurred in 3 of 21 (14%) patients after hysterectomy, (2 women with Teflon [E.I. DuPont de Nemours and Company, Wilmington, DE]. mesh; 1 woman with polyethylene terephthalate [Mersilene, Johnson & Johnson, Somerville, NJ] mesh), compared with none of the other women. Similarly, Culligan<sup>24</sup> reported mesh erosion in 3 of 11 (27%) women who underwent concomitant total hysterectomy, compared with 3 of 234 (1.3%) who did not ( $P < .001$ ). In another study Thompson reported mesh erosions in 3 of 22 (13.6%) women who underwent concomitant hysterectomy, compared with 1 of 121 (0.7%) who had sacrocolpopexy alone, and 0 of 25 who underwent supracervical hysterectomy at the time of sacrocolpopexy ( $P < .05$ ) (Thompson PK, Pugmire JE, Sangi-Haghpeykar H. Abdominal sacrocolpopexy utilizing Gore-Tex in genital prolapse: unresolved issues. Unpublished data.).

In contrast, Brizzolara and Pillai-Allen<sup>25</sup> reported no mesh erosion in 60 women undergoing sacrocolpopexy with hysterectomy compared with 1 of 64 without concurrent hysterectomy. Fedorkow and Kalbfleisch<sup>26</sup> examined early postoperative febrile morbidity in 86 women undergoing sacrocolpopexy and concomitant hysterectomy and 149 women undergoing sacrocolpopexy alone. Prophylactic antibiotics and polypropylene (Prolene, Ethicon Endo-Surgery, Inc., Cincinnati, OH) mesh were used. Of note, surgeons left the vaginal cuff open to heal by secondary intention. The authors found no difference in early febrile morbidity or length of hospitalization.

Alternately, several authors have described modifications of the sacrocolpopexy that permit preservation of the uterus.<sup>27,28</sup> Such techniques are recommended for women who wish to preserve their reproductive organs and bring the evolution of the sacral colpopexy full circle

to Arthure and Savages' early description of the sacral hysteropexy.

Much is unknown about the effect of surgical technique variations on outcome. Nonetheless, based on the experiences reported in the literature by various investigators during the past 50 years, as well as the personal experiences of the investigators, we summarize key aspects about surgical technique about which the authors are in agreement: 1) use some type of graft, rather than directly affixing the vagina or uterus to the sacrum; 2) avoid excessive tension on the anterior vagina graft, to minimize the risk of stress incontinence postoperatively; 3) decrease the risk of massive presacral hemorrhage by placing sutures through the anterior longitudinal ligament closer to the sacral promontory, rather than at S-3-S-4; 4) avoid placing layers of synthetic graft material on a denuded vaginal apex; and 5) place multiple sutures over the vaginal portion of graft to spread out tension, rather than simple fixation at the apex.

### Mesh Material

The ideal material for sacrocolpopexy would be durable over a lifetime, inexpensive, easy to use, and carry no risk of erosion, infection, carcinogenesis, or inflammation. Because such a material does not exist, the surgeon must balance durability, adverse events, and ease of use of existing graft materials. Patients in most published case studies received synthetic mesh. Synthetic meshes differ in key factors such as their pore size, filament structure, ability to evoke an acute thrombotic response, antiseptic capability, and stiffness. Recent reviews of synthetic mesh used in reconstructive gynecologic surgery are provided by Iglesia et al<sup>29</sup> and by Cosson et al.<sup>30</sup> At this time, the literature cannot answer the question of whether synthetic and biologic meshes are equally durable. It is also not clear whether specific synthetic meshes fare better than others, in terms of comfort or adverse events. In response to several case reports that detailed the care of women who developed graft erosion after sacrocolpopexy, Hurt<sup>31</sup> hypothesized in an accompanying editorial on various factors potentially related to decreased rates of mesh erosion other than the actual choice of mesh itself: improving vaginal health by treating vaginitis and using vaginal estrogen, administering perioperative antibiotics, using multiple small-gauge sutures to attach a 2-strap mesh to the full thickness of the fibromuscular vaginal wall, and extraperitonealizing the suspending strap.

Autologous fascia provides a nonimmunogenic material that is unlikely to erode. The routine use of this material is offset by the potential increased risk of incisional hernia formation (if rectus fascia is used) and undetermined durability. One study suggests that freeze-



dried, irradiated donor fascia is accompanied by a poor outcome.<sup>32</sup> Of 67 women who underwent sacrocolpopexy with this material, 53 provided follow-up data. By 1 year after surgery, 43% were failures, and by a median follow-up interval of 17 months, 83% were failures. It is of interest that in 16 patients who failed the initial surgery, the authors repeated sacrocolpopexy using synthetic mesh, and at the time of surgery found no graft between the sacrum and the vagina in 13 (81%).

In nearly all case studies, surgeons attach the mesh to the anterior longitudinal ligament with sutures (usually permanent), caudad to the promontory. Some reconstructive surgeons, particularly those using a laparoscopic approach, use bone anchors. There are no trials comparing different sacral fixation techniques. Regardless of the technique used to anchor the mesh to the sacrum, it is vital that the surgeon adhere to strict safety guidelines, because the common iliac vein, right ureter, middle sacral artery and vein, and lateral sacral venous plexus are all within 1 or 2 cm of the promontory fixation site and can be injured if not clearly identified before sutures or staples are placed.

### Bladder Function

Many women who undergo sacrocolpopexy have abnormal bladder function before surgery, including urinary incontinence (stress, urge, and mixed) and varying degrees of urinary retention. Urinary retention associated with hydroureter is generally considered an indication for prolapse treatment. In 1 case study preoperative urinary retention resolved in 31 of 35 (89%) women after prolapse surgery.<sup>33</sup> Although theoretically possible, most urodynamicists readily acknowledge practical limitations in trying to reduce prolapse optimally while the patient is voiding. Many surgeons do not formally evaluate preoperative urinary retention with electronic urodynamic testing (such as pressure-flow voiding studies), presuming that the retention is caused by the prolapse. Women with preoperative symptoms of stress incontinence require evaluation, usually with and without prolapse reduction. When urodynamic stress incontinence is confirmed without prolapse reduction in a stress-incontinent patient, concomitant incontinence procedures are considered. There are no urodynamic measures of sphincteric integrity that have been validated in this setting. Neither leak point pressures nor urethral closure pressures have been studied with and without prolapse reduction. Thus, storage phase urodynamic diagnoses other than urodynamic stress incontinence and detrusor overactivity are limited.

Women without symptoms of stress incontinence pose additional challenges. The incidence of postoperative stress incontinence after prolapse surgery is not well

established; small studies report a wide range between 8% and 60%.<sup>34–36</sup> To try to predict postoperative stress incontinence in women currently continent, some surgeons recommend reduction testing with replacement of the prolapse into the intended postoperative position. Many different prolapse reduction methods have been described, including a pessary, large cotton swab, Sims speculum, vaginal packing, ring forceps, and manual reduction. Unfortunately, the sensitivity, specificity, and predictive values for any form of reduction testing are not known. Anecdotal clinical experience suggests that when prolapse is replaced more deeply in the pelvis, stress incontinence is more likely to occur, because of flattening of the anterior vagina and urethrovesical angle. Different surgical procedures place the vaginal apex in different pelvic locations, and it is difficult to reproduce similar effects by prolapse manipulation. Also, it is not known whether reduction testing is equally effective in predicting postoperative incontinence after different prolapse surgeries.

Thus, in the continent patient, the reconstructive surgeon is left with 1 of 3 choices for this situation. The surgeon can routinely perform an anti-incontinence operation, although it is likely that some patients will be over-treated. Alternatively, the surgeon can observe postoperative symptoms and perform a second surgery for women whose stress incontinence symptoms warrant surgical treatment. Finally, a surgeon may try to predict which patients will have troublesome postoperative stress incontinence although, as noted above, the predictive value of reduction testing is unknown.

### Bowel Function

Functional disorders of the lower gastrointestinal tract are common in women with advanced prolapse.<sup>37</sup> It is difficult to sort out whether, in a given woman, prolonged defecatory dysfunction contributed to prolapse development, or whether the prolapse itself led to defecatory problems, possibly by an obstructive mechanism. Different aspects of sacrocolpopexy could either benefit or compromise defecation. Elevating the posterior vaginal wall by sacrocolpopexy may alleviate obstruction and decrease the need to splint or strain. However, it is possible that extensive dissection between the posterior vagina and the rectum, or anterior displacement of the rectosigmoid colon secondary to a concomitant culdoplasty may exacerbate or cause defecatory dysfunction.

There is limited information about postoperative bowel function. In 2 studies, the symptom of constipation decreased after sacrocolpopexy (from 64% preoperatively to 38% postoperatively in 1,<sup>38</sup> and from 36% to 26% in another<sup>39</sup>), whereas in a third study this rate



increased (from 29% to 52%).<sup>20</sup> In 2 other studies, new onset constipation was reported by 26%<sup>40</sup> and 16%<sup>41</sup> of women. One group found a marked decrease in various bowel symptoms in 12 women after surgery (from 42% to 8%<sup>42</sup>), whereas others noted minimal change (from 20 to 21%<sup>41</sup> and 46 to 52%<sup>20</sup>). Most studies did not collect information on painful defecation; in 1 exception, 26% of 30 women reported new onset of painful defecation after surgery.<sup>40</sup>

Cundiff et al<sup>16</sup> described perioperative bowel function in 19 women undergoing a sacrocolpoperineopexy, in which the posterior strap of synthetic mesh was attached to the perineal body. In short-term follow-up (mean 11 weeks), 8 of the 12 women (67%) who reported preoperative defecation problems had symptom relief.

In summary, there seems to be a high rate of both preoperative and postoperative defecatory dysfunction in women undergoing sacrocolpopexy. Our ability to counsel patients about the effect of sacrocolpopexy on their bowel function is limited due to a dearth of prospective studies and poorly described preexisting bowel dysfunction in retrospective reports, along with variability in surgical techniques, graft material, and length of follow-up and the confounding effects of age and preexisting comorbidities.

### Sexual Function

Sexual function before and after sacrocolpopexy is an understudied area, and few published reports address this in any detail. There is no clear advantage to vaginal compared with abdominal surgery in terms of maintaining sexual function. However, in women desiring future coitus who have shortened, narrowed vaginas from prior surgeries, the authors generally recommend sacrocolpopexy. Current data about sexual function after sacrocolpopexy are generally retrospective and potentially confounded by other factors implicated in the development of dyspareunia, such as concomitant perineorrhaphy, retropubic urethropexy,<sup>43</sup> and posterior colporrhaphy.<sup>44</sup> Longer follow-up intervals introduce the effect of advancing age, vaginal atrophy, development of disabilities, and attrition of sexually functional partners. In 3 reports the range of women engaging in intercourse after sacrocolpopexy ranged from 21% to 70%.<sup>20,38,40</sup> Most women who were sexually active before surgery remained so after surgery. Lack of sexual activity was most often due to the absence of a sexually functional partner.<sup>20</sup>

In a prospective randomized trial comparing sacrocolpopexy to bilateral sacrospinous suspension, Benson et al<sup>45</sup> reported a 58% rate of postoperative dyspareunia after sacrospinous suspension and no dyspareunia after sacrocolpopexy. However, confounding this issue was

the fact that women undergoing vaginal surgery had numerous concomitant procedures that may have affected this outcome.

Virtanen et al<sup>40</sup> evaluated 30 women (mean age 61 years) 3 years after sacrocolpopexy. Seven of the 16 sexually active women complained of dyspareunia, with 37.5% reporting increased and 6.25% decreased dyspareunia. Libido or sexual interest was unchanged in 4 women (25%), increased in 1 (6%), and decreased in 11 (69%). In another study 2 of 23 women (8.7%) described pain during coitus attributed to the sacral mesh fixation point.<sup>38</sup>

Conversely, there are several reports of improved sexual function after sacrocolpopexy.<sup>20,38</sup> Eight of 9 women (89%) with preoperative dyspareunia in Baessler's study reported resolution after sacrocolpopexy.<sup>38</sup> Several small case studies report the absence of de novo dyspareunia, and 1 report indicated no change in patients' abilities to achieve orgasm.<sup>42</sup> Given the sparse literature in this area, and conflicting results, preoperative counseling for sexually active women is compromised until prospective studies using validated, disease-specific sexual function instruments are available.

### Effectiveness of Sacrocolpopexy

Studies to date have reported outcomes in 2 categories: anatomic, using a variety of descriptions, and symptomatic, using a variety of symptom scales, many nonvalidated. Anatomic outcomes typically use scales to measure vaginal support, such as the Baden-Walker scale<sup>46</sup> or the more recent Pelvic Organ Prolapse Quantification system.<sup>47</sup> In older literature, subjective or nonvalidated descriptors were used. These terms include nonquantified terms such as "cystocele," "rectocele," and "enterocele," often with an undefined modifier such as "mild," "moderate," or "severe." One randomized trial created an outcome variable called "optimal" to combine important aspects of anatomy and symptoms.<sup>45</sup> Other outcome measures are variably reported and include complication and erosion rates.

Follow-up duration for most studies ranged from 6 months to 3 years. The success rate, when defined as lack of apical prolapse postoperatively, ranged from 78–100%, and when defined as no postoperative prolapse, from 58–100%. Studies reporting effectiveness of sacrocolpopexy are summarized in Table 1. When the definition of success is broadened to include the level of patient satisfaction, lack of recurrent or de novo vaginal prolapse, lack of complications or undesired symptoms subsequent to the procedure (new onset of incontinence, dyspareunia, pain, constipation, etc.), or need for additional surgical procedures, the success rate is more difficult to determine. In terms of patient satisfaction, 1 study



**Table 1.** Effectiveness of Sacrocolpopexy

Author	No. Patients (No. Lost to Follow-up, if Known)	Follow-up (mo)	Success Rate (%)	Criteria for Success	Other Prolapse Subsequently Developed (No. With Recurrent or New)	Symptoms Described at Follow-up	Comments
Arthure <sup>3</sup>	50 (2)	NS	90	No recurrence of uterine prolapse or enterocele	12 asymptomatic cystocele 4, asymptomatic rectocele		Uterus, cervical stump or cuff directly affixed to sacrum
Lane <sup>5</sup>	24	NS	92	No recurrence of prolapse			In 20 patients, synthetic mesh was stapled to the sacrum; 2 devel- oped prolapse recur- rence due to staples becoming dislodged from the sacrum
Birnbaum <sup>6</sup>	9 (0)	33	100	Good support		1 mild SUI	
Addison et al <sup>9</sup>	56 (2)	39	96	Good vaginal vault suspension in a normal axis		No reported difficulty with coitus, 6 recurrent SUI (following a concomitant RPU), 1 de novo SUI	1 patient unimproved because a presacral hemorrhage prevented successful completion of the procedure
Snyder and Krantz <sup>10</sup>	147 (15)	43	93 (108/116)	Lack of major long-term postoperative compli- cations, restoration of functional vagina in the proper axis, and no recurrence of pre- senting symptoms with at least 6 months of follow-up	24 recurrent cystocele or rectocele	38 urinary inconti- nence (23 of whom had concomitant RPU), 36 persistent bowel problems, 34 pelvic pressure	Graft attached to the entire length of the vagina in the rectovaginal septum
Lansman <sup>14</sup>	8 (0)	5.5	100	No recurrence of an enterocele or vault prolapse			
Cundiff et al <sup>16</sup>	19 (0)	11 weeks	100	No prolapse > stage II (63% stage 0, 21% stage I, 16% stage II)		8/11 bowel symptoms improved	Abdominal sacral col- poperineopexy per- formed in all patients due to posterior com- partment defects and perineal descent associ- ated with vaginal vault prolapse
Sullivan et al <sup>17</sup>	236 (31)	64	100	No recurrence of vaginal or rectal prolapse		66/78 patients had com- plete resolution of preoperative fecal incontinence; defeca- tion difficulty im- proved in 57 (76%) patients; Symptoms persisting at >90 days: 4/137 dyspa- reunia, 3 pelvic pain, 13 defecation prob- lems, 14 urinary problems	Total pelvic mesh repair involved attaching mesh strip between the perineal body and the sacrum and then attaching 2 additional strips laterally to the pubis to support the vagina and bladder

(continued)



**Table 1.** Effectiveness of Sacrocolpopexy (*continued*)

Author	No. Patients (No. Lost to Follow-up, if Known)	Follow-up (mo)	Success Rate (%)	Criteria for Success	Other Prolapse Subsequently Developed (No. With Recurrent or New)	Symptoms Described at Follow-up	Comments
Pilsgaard and Mouritsen <sup>20</sup>	35 (4)	24	97	No recurrent vault prolapse	4 rectocele	27/33 cured of prolapse symptoms. Resolu- tion of urge inconti- nence in 9/12, fre- quency in 12/15, nocturia in 5/10, and “voiding problems” in 14/14. One patient developed fecal in- continence, and 5 developed urge in- continence. No coital problems in 7/7. Difficulty evacu- ating rectum in 10.	The 1 patient with recurrent vault prolapse was noted to have the mesh detached from the promontory
Feldman and Birnbau <sup>22</sup>	21 (0)	16	95	Adequate vaginal sup- port, sufficient vaginal depth and appropriate vaginal axis	2 mild cystocele 1 each: small anterior enterocele, first-degree rectocele		The patient with the failure had apparent detachment of the graft from the apex based upon exam
Imparato et al <sup>23</sup>	71 (8)	NS	78	Excellent, well- suspended vault on exam			50 had direct attachment of the vaginal apex to the anterior sacrum
			16	Good vault suspension, but asymptomatic vaginal “relaxation”			
Culligan et al <sup>24</sup>	245	61.2	85	Any POP-Q point $\geq 2$	22 anterior seg- ment failure 14 posterior seg- ment failure 2 both anterior and posterior failure	PSI scores range 4.5– 6.1 Quality of life scores range 0.2–0.84	No apical failures observed
Brizzolara and Pillai-Allen <sup>25</sup>	124	36	98	No recurrent vault prolapse	12 recurrences of $\geq$ grade III or symptomatic prolapse or both (sites other than the vault; grade I and II not re- ported)		
van Lindert et al <sup>27</sup>	61	32	97	No recurrent vaginal prolapse	2 recurrences of unsupported areas of the vaginal wall	1 persistent urinary incontinence	8 patients had preserva- tion of the uterus

*(continued)*

reported mean postoperative visual analog scale scores of 7.2–8.5 (out of 10) for various outcomes.<sup>40</sup> In a questionnaire study 1–13 years after surgery (median 4 years), 23 of 72 (32%) patients considered themselves to be “fully cured,” whereas 28 (39%) of patients felt “con-

siderable improvement,” and 21 (29%) of patients felt “no improvement.”<sup>67</sup> Many studies report satisfaction or complete relief of symptoms between 85% and 100%, although outcome tools are generally not described (Table 1).



**Table 1.** Effectiveness of Sacrocolpopexy (*continued*)

Author	No. Patients (No. Lost to Follow-up, if Known)	Follow-up (mo)	Success Rate (%)	Criteria for Success	Other Prolapse Subsequently Developed (No. With Recurrent or New)	Symptoms Described at Follow-up	Comments
Costantini et al <sup>28</sup>	21 (0)	31.6	90	Overall satisfaction per postoperative questionnaire; in all patients prolapse was reduced on examination post-operatively	6 first-degree cystocele, 1 rectocele	20 irritative symptoms improved, 2 new or persistent constipation, 5 nonspecific pelvic pain; No dyspareunia, 3/11 persistent slight incontinence	7 patients underwent hysteroscaptopexy
Baessler and Schuessler <sup>38</sup>	33 (2)	26	100	No recurrence of vaginal vault prolapse, enterocele or anterior rectal wall prolapse	16/28 patients with preoperative rectocele recurred, 1 rectocele developed de novo (2 patients asymptomatic)	12/32 outlet constipation, 3/23 dyspareunia, 7.2 satisfaction on visual analog scale (mean of 10)	Attempted to correct rectoceles abdominally with extension of the graft
Maher et al <sup>39</sup>	47 (1)	24	76% objective 94% subjective	Objective: No POP beyond halfway point Subjective: No symptoms of POP	Cystocele-3 Vault-2 Enterocele-7 Rectocele-8	Preop voiding dysfunction resolved in 7/9. Preop dyspareunia resolved in 5/9 and developed in 2/10	Results are from a RCT comparing sacrocolpopexy to sacrospinous ligament suspension
Virtanen et al <sup>40</sup>	30 (3)	36	85	Good vaginal vault support on exam	Moderate or severe cystocele, 5; enterocele, 4; rectocele, 4; chronic perineal laceration, 4	Dyspareunia (increased postoperatively), 6; constipation, 7; Pain and pressure in rectum, 7; new stress incontinence, 5	2 patients with recurrences had failure at the vaginal apex (absorbable sutures used)
Geomini et al <sup>41</sup>	45 (5)	38	93	No vault prolapse	10 moderate enterorectocele 2 cystocele	56% no symptoms related to prolapse, 5 de novo constipation, 6/8 resolution of defecation problems; No de novo urinary incontinence	Culdoplasty done only selectively; 2/3 failures were noted to be a result of graft detachment from the vagina (staples and a tacker used for attachment)
Marinkovic and Stanton <sup>42</sup>	12 (0)	39	83	No recurrent prolapse (anterior, posterior, or vault)	1 grade 1 cystocele, 1 grade 1 rectocele	Median visual analog scale score, 8/10 1 each: de novo SUI, de novo urgency No de novo dyspareunia, de novo defecation difficulty	

*(continued)*

New or recurrent prolapse at sites other than the vaginal apex is also an important outcome to consider. If success is defined as the lack of any significant vaginal prolapse, regardless of the compartment (anterior, posterior, apical), the rate drops. Depending on the stage of

prolapse considered significant, success rates using this definition range from 58% to 100%. A few examples illustrating the discrepancy between apical success and overall success follow. Geomini et al<sup>41</sup> reported no apical prolapse in 93% of women after surgery; however, 12 of



**Table 1.** Effectiveness of Sacrocolpopexy (*continued*)

Author	No. Patients (No. Lost to Follow-up, if Known)	Follow-up (mo)	Success Rate (%)	Criteria for Success	Other Prolapse Subsequently Developed (No. With Recurrent or New)	Symptoms Described at Follow-up	Comments
Valaitis and Stanton <sup>44</sup>	41 (2)	21	88	No third degree enterocele on exam, no symptomatic enterocele		4 dyspareunia (all had posterior repairs) 5 persistent vaginal discharge (all had posterior repairs), 5 new or worse SUI, 3 new or worse detru- sor overactivity	One failure had direct attachment of the vagina to the sacrum
Benson et al <sup>45</sup>	40	60	58 (another 26% of patients had "satis- factory" outcomes)	Patient asymptomatic, vaginal apex supported above the levator plate, no protrusion beyond the hymen	4 cystocele, 2 rectocele, 1 enterocele Only those that required reoperation were men- tioned	No dyspareunia, 23% developed incontinence	All patients had sacrocolpopexy and paravaginal repair Results are from a RCT comparing sacrocolpopexy to sacrospinous suspension
Falk <sup>48</sup>	3 (0)	≤ 36	100	Cured		"Normal" sexual inter- course postopera- tively in all	Uterus, cervical stump or cuff directly affixed to sacrum
Rust et al <sup>49</sup>	12 (0)	24	100	No vaginal vault prolapse	1 urethrocele	No SUI	
Cowan and Morgan <sup>50</sup>	39	30	97	Good vaginal support, no pelvic complaints	1 vault	No new incontinence seen in women with- out concomitant RPU. No distur- bances with sexual intercourse	Surgical failure involved distal detachment of mesh from vagina
Symmonds et al <sup>51</sup>	17 (1)	NS	94	Good vaginal support and function			
Grundsell and Kligman <sup>52</sup>	9 (0)	46.8	100	No recurrences of vault prolapse	Moderate cystocele, 1	No dyspareunia or SUI	
Kaupilla et al <sup>53</sup>	14 (0)	30	71	Adequate vaginal support on exam	2 small cystocele		6 of 14 patients had direct attachment of the vaginal apex to presacral fascia, and 4 of these recurred. None of 8 patients in whom graft was used recurred
Kaupilla et al <sup>54</sup>	9 (0)	50	100	Excellent vaginal support on exam			Fascial grafts used to suspend the cuff in all patients
Drutz and Cha <sup>55</sup>	15 (0)	28	93	Well-supported vault	2 grade I rectocele	1 urge incontinence	The 1 patient with recurrent vault prolapse was the only 1 in whom the vagina was directly attached to the promontory

*(continued)*

40 (30%) developed a moderate enterorectocele postoperatively. The authors attributed this to the selective use of concomitant culdoplasty and recommended in their report that culdoplasty routinely be done with sacrocol-

popexy. Brubaker<sup>66</sup> examined 65 patients, most of whom underwent both sacrocolpopexy (with posterior graft attachment only) and abdominal anterior compartment surgery, and found that 19 (29%) had persistent or



**Table 1.** Effectiveness of Sacrocolpopexy (*continued*)

Author	No. Patients (No. Lost to Follow-up, if Known)	Follow-up (mo)	Success Rate (%)	Criteria for Success	Other Prolapse Subsequently Developed (No. With Recurrent or New)	Symptoms Described at Follow-up	Comments
Angulo and Kligman <sup>56</sup>	18 (0)	13	100	Free of symptoms that caused consultation and no degree of prolapse found on vaginal exam			
Baker et al <sup>57</sup>	59 (6)	6	100	No complaint of protrusion from the vagina	Cystocele, 6/51; rectocele, 4/51	Complaint of pressure, 8; impaired coitus, 8; incontinence, 7; other urinary complaints, 10; pelvic pain, 5; difficulty defecating, 2	
Maloney et al <sup>58</sup>	10 (0)	26	90	Complete relief of symptoms		No dyspareunia	
Creighton and Stanton <sup>59</sup>	23	17	91	No vault prolapse on exam and no complaints of prolapse		No de novo SUI, 1 dyspareunia	
Timmons et al <sup>60*</sup>	163	33	99	Good vaginal vault support	3 recurrent enteroceles	18/71 SUI after concurrent anterior colporrhaphy or RPU	
Traiman et al <sup>61</sup>	9 (0)	36.5	91	Good results on exam		No dyspareunia	1/2 patients with direct attachment of the vagina to the sacral promontory failed
Iosif <sup>62</sup>	40 (0)	36	97	Complete symptom relief, no vault prolapse	2 rectocele, 1 first-degree cystocele	No dyspareunia	Patient with failure had detached graft from apex
Grunberger <sup>63</sup>	62 (14)	75.6	94	No moderate vaginal vault prolapse on exam	Not stated	7 slight "pain" in the sacral region; No dyspareunia, 12/33 recurrent mild SUI	42 patients had direct attachment of the vagina to the sacral promontory, 12 had permanent "suture bridges," 8 had Lyodura loops
Lecuru et al <sup>64</sup>	203	32.5	86.7–100 53.3–80.5	Anatomically good results Functionally good results			The range of success is due to 4 different techniques which were compared
Nezhat et al <sup>65</sup>	15 (0)	3–40	100	Complete relief of symptoms, excellent vaginal vault support		No patients had coital difficulty postoperatively	All cases done laparoscopically; 1 converted to laparotomy
Brubaker <sup>66</sup>	65 (0)	3	71	No anterior or apical prolapse	19 anterior compartment defects (17 asymptomatic)	45% symptom-free postoperatively, 4 SUI, 18 urge incontinence; No new onset of voiding dysfunction	63/65 patients had abdominal anterior compartment repair at the time of the sacrocolpopexy

*(continued)*

**Table 1.** Effectiveness of Sacrocolpopexy (*continued*)

Author	No. Patients (No. Lost to Follow-up, if Known)	Follow-up (mo)	Success Rate (%)	Criteria for Success	Other Prolapse Subsequently Developed (No. With Recurrent or New)	Symptoms Described at Follow-up	Comments
de Vries et al <sup>67</sup>	101 (29)	48	32	Fully cured (patient satisfaction based upon questionnaire)		15 de novo complaints of pain (abdominal, vaginal or anal) 6 de novo "prolapse- related problems," 4 SUI	Questionnaires sent to patients to evaluate pain, prolapse-related complaints and functional disorders
			39	Considerable improvement			
			29	No improvement			
Hardiman and Drutz <sup>68</sup>	80	47	99	No recurrent vault prolapse		1 SUI	
Ross <sup>69</sup>	19 (2)	12	100	No recurrent vault pro- lapse at 6 weeks or 1 year postoperatively	3 grade 1 or 2 cystocele, 2 grade 1 cystocele	No sexual dysfunction, 1 mild SUI	All patients underwent laparoscopic sacrocol- popexy, Burch colpo- suspension, and modi- fied culdoplasty, with paravaginal defect re- pairs and posterior colporrhaphy added as indicated
Ocelli et al <sup>70†</sup>	271 (54)	66	97.7	Cured for prolapse		32/191 recurrent SUI	
Patsner <sup>71</sup>	175 (0)	≥ 12	97	No "mesh failures"			Comparison of patients with gynecologic can- cers with those without
Schettini et al <sup>72</sup>	15 (0)	15	100	High position of the vaginal apex			
Sze et al <sup>73</sup>	56 (9)	23	81	No recurrent prolapse to or beyond the hymen	5 anterior wall defects, 4 posterior wall defects	2 recurrent SUI, 4 urge incontinence	All 9 patients with recurrent prolapse were symptomatic
Diana et al <sup>74</sup>	15	20	100	No relapse of the treated prolapses		1 urinary frequency, 4 hypogastric "sense of heaviness," 11/11 no coital problems	
Fox and Stanton <sup>75</sup>	29	14	100	> Stage I prolapse at any site	27% stage I vault prolapse, 7% stage I rectocele	No new SUI, 10% postoperative prolapse symptoms	
Nieminen and Heinonen <sup>76</sup>	26 (6)	105	64	Any symptomatic prolapse, or asymptomatic stage II-IV prolapse	7 cystocele, 6 rectocele, 4 enterocele, 3 vault prolapse	12% new SUI, 19% bowel dysfunction (mostly obstipation), 1/9 new-onset dyspareunia, 4/9 intercourse more comfortable	Direct attachment of the vagina to the sacrum in 4 patients
Winters et al <sup>77</sup>	20 (0)	11	100	No recurrent enterocele or vault prolapse	3 grade II cystocele, 3 grade II rectocele	3 SUI despite concomitant RPU or pubovaginal sling	
Scarpero et al <sup>78</sup>	20	11	100	No recurrent enterocele or vault prolapse	3 grade II cystocele, 3 grade II rectocele	3 persistent SUI despite concomitant RPU	All patients underwent sacrocolpopexy, Hal- ban's culdoplasty, and paravaginal repair
Collopy and Barham <sup>79</sup>	89 (0)	56.7	100	No recurrence of rectal or vaginal vault prolapse	9 minor degree of prolapse of the lower third of the vagina	No new symptoms of any type	All had concomitant culdoplasty

*(continued)*

**Table 1.** Effectiveness of Sacrocolpopexy (*continued*)

Author	No. Patients (No. Lost to Follow-up, if Known)	Follow-up (mo)	Success Rate (%)	Criteria for Success	Other Prolapse Subsequently Developed (No. With Recurrent or New)	Symptoms Described at Follow-up	Comments
Cosson et al <sup>80</sup>	77 (12)	12	94	No evidence of clinical prolapse	1 first-degree cystocele (later became third degree), 1 first-degree "hysterocoele"	20/67 persistent SUI	All patients had a laparoscopic sacrocolpopexy with other procedures as indicated; 6 other patients had attempted laparoscopic surgery, but required conversion to a laparotomy
Lefranc et al <sup>81</sup>	85 (0)	126 (median)	90.6	No relapse of any prolapse	2 vaginal vault prolapse, 5 cystocele, 1 rectocele	27% relapsing SUI; No SUI among those previously continent	All patients without preoperative SUI had a prophylactic Burch procedure done
Leonardo et al <sup>82</sup>	25 (0)	48	100	No recurrent prolapse			
Lindeque and Nel <sup>83</sup>	262 (0)	≥16	99	No vaginal vault prolapse	6 rectocele, 4 repeat enterocele, 2 cystocele		1/3 failures due to graft detachment from vagina
Medina et al <sup>84</sup>	97 (1)	19	90	< Grade I prolapse	5 each: vault prolapse, cystocele, 1 rectocele	6 de novo urinary incontinence	Cause of 1 failure was graft detachment from the vagina (cause of other 4 unknown)
Reddy and Malik <sup>85</sup>	11 (0)	60	100	No prolapse symptoms or vault prolapse based upon patient questionnaire	2 cystocele	6 de novo SUI	
			64 36	Satisfied Considerable improvement			
Roovers et al <sup>86</sup>	12	18	92	No symptomatic genital prolapse	1 stage II cystocele		All patients had sacrocolpopexy and RPU
			55	Satisfied with the result of surgery			
Sanz and Veroska <sup>87</sup>	11	12–24	100	Excellent vaginal support, no recurrence of prolapse			A suture anchor system was used for placement of the suture in the mesh at the sacrum
Podratz et al <sup>88</sup>	50 (6)	70	70	Asymptomatic (including no incontinence) and durable repair by exam	Mild to moderate cystocele or rectocele, 5; enterocele, 1	3 had dyspareunia postoperatively, although 2 had compromised vaginas due to multiple prior vaginal procedures, and the other patient had this complaint before surgery. De novo SUI, 2/25; persistent SUI, 6	

*(continued)*

new anterior support defects postoperatively, despite excellent apical support. Baessler<sup>38</sup> reported that although the vaginal apex was well supported postoperatively in all patients, of 28 women with a preoperative rectocele, 16 (57%) recurred, despite extending the graft down the posterior vagina. These and other studies summarized in Table

1 point out that although sacrocolpopexy is effective at correcting apical prolapse, the optimal way to address all potential defects is unknown and women remain at risk for prolapse at other vaginal sites.

A pertinent clinical question is whether durability differs between sacrocolpopexy and vaginal procedures



**Table 1.** Effectiveness of Sacrocolpopexy (*continued*)

Author	No. Patients (No. Lost to Follow-up, if Known)	Follow-up (mo)	Success Rate (%)	Criteria for Success	Other Prolapse Subsequently Developed (No. With Recurrent or New)	Symptoms Described at Follow-up	Comments
Hilger et al <sup>89</sup>	69 (31)	164	74	Subsequent POP operation or a positive response to question 5 on the PFDI <sup>†</sup>	NS	5/14 patients had "some-what" or "moderate" pain with intercourse; 28/38 patients had SUI at the time of the questionnaire; 21/28 of these patients had an incontinence procedure at the time of sacrocolpopexy	
Lo and Wang <sup>90</sup>	52 (not clear)	25	94	No prolapse > Stage II	Cystocele-2 Vaginal vault prolapse-1	2/52 de novo SUI, 1/11 sexually active women had new dyspareunia	Results are from a RCT comparing sacrocolpopexy to sacrospinous ligament suspension

NS, not stated; SUI, stress urinary incontinence; RPU, retropubic urethropexy; POP-Q, Pelvic Organ Prolapse Quantification system; POP, pelvic organ prolapse; RCT, randomized clinical trial.

\* Some patients also included in Addison's study.

<sup>†</sup> Question 5 on the Pelvic Floor Distress Inventory: "Do you usually have a bulge or something falling out that you can see or feel in the vaginal area?"

for pelvic organ prolapse. At this time, there are only 3 randomized trials that compare the 2 approaches, and results of the 3 differ. Benson and Lucente<sup>45</sup> randomly assigned 88 women to undergo either sacrocolpopexy or bilateral sacrospinous vault suspension and paravaginal repair. Numerous concomitant procedures were performed based on the surgeon's judgment. They included the following in the vaginal route group: needle suspension urethropexy (42%), McCall culdoplasty (27%), hysterectomy (50%), anterior colporrhaphy (33%), autologous sling urethropexy (21%), posterior colporrhaphy (67%), Parks levatorplasty (42%), and 6% "other" procedures. The 40 women randomly assigned to the abdominal approach received the following procedures: Burch urethropexy (35%), Halban culdoplasty (48%), hysterectomy (50%), anterior colporrhaphy (30%), Macer wedge colporrhaphy (15%), autologous sling urethropexy (5%), posterior colporrhaphy (50%), Parks levatorplasty (45%), and 18% "other" procedures. Outcomes were termed "optimal" when women were free of prolapse symptoms, the vaginal apex remained above the levator plate, and no part of the vagina prolapsed beyond the hymen, "satisfactory" when women were free of prolapse symptoms and the prolapse was improved from the preoperative status but did not meet the criteria for optimal surgical effectiveness, and "unsatisfactory" if they had symptomatic vaginal apex descent more than 50% of its length or vaginal protrusion beyond the hymen.

Enrollment was halted earlier than planned when interim analysis showed disparity in outcomes between the groups. Mean follow-up was 2.5 years (range 1–5.5 years). The vaginal group experienced 29% optimal, 38% satisfactory, and 33% unsatisfactory surgical outcomes, compared with the abdominal group, which had 58% optimal, 26% satisfactory, and 16% unsatisfactory outcomes. Surgical failures occurred sooner in the vaginal group (mean 11.2 months, range 2–47 months) compared with the abdominal group (mean 22.1 months, range 4–53 months).

In a second randomized trial Lo and Wang<sup>90</sup> randomly assigned 138 women with stage III or greater vaginal vault or uterine prolapse to either a unilateral sacrospinous ligament suspension or to abdominal sacrocolpopexy. Optimal effectiveness was defined as postoperative prolapse less than stage III. One hundred eighteen women (85%) were followed up for a mean of 2.1 years. Of the 52 women with follow-up data available who underwent sacrocolpopexy, concomitant procedures included hysterectomy in 33 (63.5%) and posterior colporrhaphy in 19 (36.5%). Of the 66 women who underwent sacrospinous suspension, 20 (30.3%) underwent a hysterectomy, and all also underwent anterior and posterior colporrhaphies. Optimal effectiveness (as defined above) was seen in 80.3% of women in the vaginal group and 94.2% of those in the abdominal group ( $P = .03$ ).



Most recently, Maher and colleagues<sup>39</sup> randomly allocated 95 women with posthysterectomy vaginal vault prolapse to or beyond the introitus to undergo either abdominal sacrocolpopexy or sacrospinous ligament suspension. Of the 47 women who underwent abdominal sacrocolpopexy, concomitant procedures included posterior colporrhaphy in 11 (23%), Burch colposuspension in 14 (30%), paravaginal repair in 19 (40%), and Moschcowitz culdoplasty in 20 (43%). Of the 48 women who underwent sacrospinous ligament suspension, concomitant procedures included posterior colporrhaphy in 44 (92%), anterior colporrhaphy in 21 (44%), enterocele repair in 28 (58%), and Burch colposuspension in 15 (31%). Objective success was defined as no vaginal prolapse beyond the halfway point of the vagina during examination (the Pelvic Organ Prolapse Quantification system was not used). Women with no symptoms of prolapse were considered subjective successes. The investigators found no statistically significant difference in either objective ( $P = .48$ ) or subjective ( $P = .19$ ) success 2 years after the procedure, with respective rates of 76% and 94% in the abdominal group and 69% and 91% in the vaginal group. While not statistically significant, 17% (7 of 43) of women in the vaginal group had prolapse to the introitus postoperatively compared with 4% (2 of 46) of those in the abdominal group and 14% (6 of 43) of women in the vaginal group had postoperative cystoceles compared with 7% (3 of 46) of women in the abdominal group. Mean patient satisfaction with the surgery was 85% in the abdominal and 81% in the vaginal group. Further trials are needed to determine not only which procedure is most durable, but more importantly, which surgical approach is optimal for a given woman, bearing in mind considerations of effectiveness, complications, and quality of life in various domains.

### Complications After Sacrocolpopexy

**Intraoperative and Perioperative Complications.** In many of the articles searched, complications were not included in outcomes reported. Complication rates are rarely assessed completely in retrospective studies and may differ dramatically in various studies because of extrinsic factors, such as length of hospital stay. Publications generally provided no information that might help assess whether certain complications were avoidable (for example, antibiotic use and wound infection). Despite these limitations, reviewing the literature provides a qualitative view of the rates of various complications. In the following literature summary, we compiled only the reported complications; thus, if an author did not specifically state that a particular complication did not occur, we did not substitute zero for the numerator but instead excluded that article

from the summary statistics. Because of the wide range of rates, we provide the median rate for each complication, as well as the range. The most common reported complication was urinary tract infection, with a median rate of 10.9% (2.5% to 25.9%).<sup>10,17,20,22,38,40,44,62,63,68,69,81,90</sup> Wound problems, such as infection, hematoma, or superficial separation, followed 4.6% of surgeries (0.4% to 19.8%).<sup>6,16,17,22,24,25,38,39,45,60,62,63,67,68,50,55,77,88</sup> Hemorrhage or transfusion or both occurred during 4.4% (0.18% to 16.9%) of sacrocolpopexies.<sup>10,11,20,24,38,39,41,44,45,48,53-55,58,61-65</sup> Intraoperative complications included cystotomy in 3.1% (0.4% to 15.8%),<sup>11,16,24,39,45,60,67,69,75,88,83</sup> enterotomy or proctotomy in 1.6% (0.4% to 2.5%),<sup>11,45,60,63,83</sup> and ureteral injury in 1.0% (0.8% to 1.9%).<sup>24,25,60,90</sup> Postoperative ileus was reported in 3.6% (1.1% to 9.3%).<sup>11,17,40,45,50,63,67,73,77,83,90</sup> A deep venous thrombus or pulmonary embolus occurred in 3.3% (0.4% to 5.0%).<sup>24,28,57,77</sup> After surgery, 1.1% (0.6%-8.6%) required reoperation for small bowel obstruction,<sup>7,20,24,25,42,60,79,83,84</sup> and 5.0% (0.4% to 15%) underwent incisional hernia repair.<sup>27,39,76,79,83,88</sup> Uncommonly reported complications included transient femoral nerve injury, subcutaneous drain separation, and pseudomembranous colitis (all occurring in 1 of 56 women),<sup>9</sup> obturator nerve injury (1 in 40),<sup>45</sup> foot drop (1 in 29),<sup>75</sup> and fascial dehiscence (1 in 245).<sup>24</sup> In addition, there have been case reports of vertebral osteomyelitis and gluteal necrotizing myofascitis.<sup>20,38,42</sup> Although uncommon, presacral hemorrhage is one of the most worrisome intraoperative complications. Some surgeons advocate tacking the graft to the ligament, under the assumption that minimizing dissection may decrease the risk of hemorrhage.<sup>87</sup> Others recommend careful dissection to avoid lacerating an unseen vessel. Strategies to treat presacral hemorrhage include orthopedic bone thumbtacks, bone wax, or a figure eight stitch.<sup>91</sup>

**Mesh Erosion.** Mesh erosion is uncommon and can occur with the use of any type of synthetic graft material. Because of the short follow-up interval reported in most studies, the actual rate is not known. No randomized trials compare erosion rates after implantation of different types of mesh. The overall rate of mesh erosion was 3.4% (70 of 2,178). Some authors did not report the specific type of mesh used; in those that did, we provide mean erosion rates for each reported mesh type used in sacrocolpopexy: autologous or cadaveric fascia or dura mater, 0 of 88 (0%);<sup>20,25,40,53,58,83</sup> polypropylene (Prolene, Ethicon Endo-Surgery, Inc.) 1 of 211 (0.5%);<sup>20,25,57,72,74</sup> polyethylene terephthalate (Mersilene, Johnson & Johnson), 25 of 811 (3.1%);<sup>15,18,20,81,59,90,92,93</sup> Gore-Tex (W.L. Gore & Associates, Inc., Flagstaff, AZ), 12 of 350 (3.4%);<sup>20,27,38,40,83</sup> Teflon (E.I. DuPont de Nemours and Company), 6 of 119 (5.5%);<sup>6,23,44,75,88</sup> and polyethylene (Marlex, Phillips



Sumika Polypropylene Co., Houston, TX) 20 of 402 (5.0%).<sup>17,55,71,75,77,93</sup> When specifically stated by the authors, we summarized the rate of reoperations for mesh-related problems. Of 20 reports with a total of 1,556 women, 47 (3.0%) were operated for mesh erosion or infection.<sup>6,15,17,20,24,27,39,41,44,50,55,59,60,62,71,79,83,85,88,90</sup>

**Reoperations for Pelvic Floor Disorders.** The rate of reoperation to treat persistent, recurrent or de novo pelvic floor disorders depends on the various factors, including surgical technique, concomitant procedures, patient characteristics that may predispose to failure and duration of follow-up. In reported studies patients were followed up for varying lengths of time, with follow-up as short as 2 months in several studies and as long as 18 years for 1 patient. The longest median follow-up duration in the reported studies was 5.3 years.<sup>17</sup> Reoperation rates, when reported, were reported as a total number over the entire period.

The median reoperation rate for pelvic organ prolapse in the studies that reported this outcome was 4.4% (0–18.2%) during follow-up intervals that ranged from 6 months to 3 years.<sup>6,20,24,40,41,45,50,53,55,60,61–63,79,83,84</sup> The majority of reoperations were for prolapse of the anterior or posterior compartment, rather than the apex. “Total pelvic mesh repair” as described by Sullivan<sup>17</sup> had a high reoperation rate, with 73 of 236 women (31%) having surgery for bladder-related symptoms and 58 (25%) for anorectal mucosal prolapse or rectocele. It is unclear from the article whether some of these patients fell into both categories.

In addition to reoperation for recurrent prolapse, women are also at risk for reoperation to treat either persistent or de novo stress urinary incontinence. Information is insufficient to state the proportion of these women who had an anti-incontinence procedure at the time of the sacrocolpopexy. Of studies that specifically described operations for stress incontinence during the follow-up period, the median rate of this event was 4.9% (1.2% to 30.9%).<sup>10,17,24,27,39,40,44,60,76,78–80,85,88</sup>

### Laparoscopic Sacrocolpopexy

Many small studies demonstrate the feasibility of laparoscopic sacrocolpopexy, although this has not replaced the traditional laparotomy approach. There have been no randomized comparisons of laparoscopic and open sacrocolpopexies. Most case studies that describe laparoscopic sacrocolpopexy are small, with 4 to 19 subjects and an average of 1 year follow-up.<sup>69,65,80,94–97</sup> In the largest case study Cosson et al<sup>80</sup> reported that 62 of 63 (94%) women followed up demonstrated no evidence of clinical prolapse at 12 months. Nezhat<sup>65</sup> reported a cure rate of 100% in 15 women at 3–40 months. Ross re-

ported no apical prolapse recurrence in 15 of 19 (79%) patients 1 year after surgery; 2 (13%) developed recurrent paravaginal defects and 3 (20%) developed rectoceles.<sup>69</sup> Dorsey and Sharp<sup>94</sup> reported 100% satisfactory apical suspension in 9 women, although the length of follow-up was not reported. After a maximum of 2 to 3 months follow-up, Drent<sup>96</sup> reported a 100% “successful outcome” in 5 women, although success was not defined.

Complications were reported in 4 of the original articles cited above. Of 77 women reported by Cosson et al<sup>80</sup> 1 had a rectal injury, 2 had bladder injuries, and 3 underwent reoperations for bleeding complications, including 1 perioperative hemorrhage requiring conversion to laparotomy. Ross<sup>69</sup> reported similar injuries. In Nezhat’s study,<sup>65</sup> 1 of 15 patients required conversion to laparotomy for presacral bleeding. Cosson et al,<sup>98</sup> in a separate publication, reported the complication of staple erosion into the vagina after stapling mesh to the vagina with the Endopath Reticulator (Ethicon Endo-Surgery, Inc.) and subsequently do not recommend using staples on the vagina. Larger trials with careful follow-up are needed to understand whether, for this particular surgery, the laparoscopic and open approaches are similar in durability and complication rates.

### CONCLUSION

Randomized trials would provide important answers to questions that arise once sacrocolpopexy is chosen by the clinician and the patient as the “best” operation for her prolapse. Which material provides the optimal balance between effectiveness and the risk of complications such as mesh erosion? How much of the vagina should be incorporated into the graft material? Is there a difference in the various configurations of graft material that cover the vagina? Should the graft be covered with peritoneum? Should culdoplasty or paravaginal repair be routinely done? Is sacrocolpoperineopexy superior to sacrocolpopexy for providing perineal support, and if so, are the 2 procedures equally safe? Currently, the Pelvic Floor Disorders Network, a cooperative agreement network sponsored by the National Institute of Child Health and Human Development, is conducting a randomized clinical trial to evaluate whether a standardized modified Burch colposuspension, when added to planned abdominal sacrocolpopexy, improves the rate of stress continence in women without preoperative symptoms of stress incontinence. The value of preoperative urodynamic testing with and without prolapse reduction to predict postoperative stress incontinence is also being tested.

Despite the evidence that sacrocolpopexy is an effective surgical treatment for apical prolapse, there are many questions that will remain unanswered without further randomized trials comparing abdominal and vag-



inal approaches to pelvic organ prolapse repair. Such trials are challenging to do, given surgeons' strongly held beliefs. For example, in the absence of substantial level I evidence, some of this article's authors believe that sacrocolpopexy is superior in younger women, when durability is the predominant goal, but that older women are best served by vaginal approaches, when safety and ease of recovery may be the predominant goals. However, other authors of this article base their clinical practice on contradictory beliefs and believe vaginal surgery is best suited to younger women who may have better-quality tissue than older ones. Improved prospective data that accurately describe outcomes and complications of both approaches in different patient populations is needed, so that we can counsel patients based on facts, rather than on surgeons' beliefs.

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Reprints are not available. Address correspondence to: Ingrid East Nygaard, MD, University of Iowa, Department of Obstetrics and Gynecology, 200 Hawkins Drive, 2 BT, Iowa City, IA 52242; e-mail: ingrid-nygaard@uiowa.edu.

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## APPENDIX

### **Pelvic Floor Disorders Network Steering Committee members**

Linda Brubaker, MD

Department of Obstetrics and Gynecology, Loyola University Medical Center, Maywood, Illinois

Geoff Cundiff, MD

Department of Obstetrics and Gynecology, Johns Hopkins University, Baltimore, Maryland

Paul Fine, MD

Department of Obstetrics and Gynecology, Baylor College of Medicine, Houston, Texas

Ingrid Nygaard, MD

Department of Obstetrics and Gynecology, University of Iowa, Iowa City, Iowa

Holly Richter, PhD, MD

Department of Obstetrics and Gynecology, University of Alabama, Birmingham, Alabama

Anthony Visco, MD

Department of Obstetrics and Gynecology, University of North Carolina at Chapel Hill, Chapel Hill, North Carolina

Halina Zyczynski, MD

Department of Obstetrics and Gynecology, University of Pittsburgh, Pittsburgh, Pennsylvania

Morton B. Brown, PhD

Department of Biostatistics, University of Michigan, Ann Arbor, Michigan

Anne Weber, MD

National Institute for Child Health and Human Development, Bethesda, Maryland

